

### **Remarks**

Claims 6 and 8-12 are presently pending in the application, with claim 6 being currently amended, claims 11 and 12 being newly added, and previously withdrawn claims 1-5 and 7 being canceled without prejudice. Applicant reserves the right to pursue the subject matter of the canceled claims in one or more continuing applications.

Independent claim 6, which is the only independent claim, has been amended to more clearly define Applicant's invention, particularly in view of the 35 U.S.C. §112, first paragraph, rejection addressed further below. More specifically, claim 1 now recites a biomaterial that includes, in part, a film that has an apatite forming ability in an artificial body fluid. [underlining for emphasis]. Support for the amendment can be found throughout the specification and, more specifically, at least at page 4, lines 4-8; page 10, line 24 to page 11, line 6; and the Examples, for example.

In addition, new dependent claim 11, which depends directly from independent claim 6, further specifies that apatite is formed on a portion of a surface of the film of the biomaterial when the biomaterial is immersed in the artificial body fluid. And, new dependent claim 12, which depends from claim 11, specifies that apatite is formed across the entire surface of the film of the biomaterial when the biomaterial is immersed in the artificial body fluid. Support for the new claims can be found throughout the specification and, more specifically, at least at page 11, lines 7-12; the Examples; and Table 1, for example.

Concerning Examiner's request on page 2 of the Official Action to provide a more descriptive title, Applicant has changed the Title of the Invention to "Biomaterial Having Apatite Forming Ability".

Also in the Official Action, Examiner acknowledges receipt of the information disclosure statement (IDS) filed on August 22, 2003. With respect to that IDS, Examiner alleges that a translation was indicated but not submitted for Japanese reference no. 2-13580. In view thereof, Examiner states that he could not consider that reference. *See* Official Action, page 2. However, Applicant submits that the Examiner is mistaken. Rather, the English translation of the claims was actually submitted as is evidenced by the fact that it is readily viewable online in the U.S. Patent and Trademark Office database via Public Pair under the Image File Wrapper tab for this application. Specifically, the translation at issue consists of a single page and appears to have been incidentally attached as the last page, i.e., page 19 of 19, of the 8-22-03 .pdf submission of Japanese reference no. 2002-105676. Applicant apologizes for any confusion this may have caused. Regardless, Applicant requests that Examiner now consider the document in view of its previous submission and indicate such by properly initialing next to the document on the IDS.

**35 U.S.C. §112, first paragraph**

Claims 6 and 8-10 stand rejected under 35 U.S.C. §112, first paragraph, insofar as the specification allegedly fails to clearly define the term "apatite forming ability". *See* Official Action, page 3. Clarification is requested by Examiner insofar as it allegedly is unclear what this entails.

In reply thereto, Applicant submits that the term "apatite forming ability", along with being well known and understood by one of ordinary skill in the art, as evidenced by Exhibits A-C attached hereto and further discussed below, is not at all unclear but clearly discernible upon review of the specification. Thus, because the term is not unclear, the rejection must be withdrawn. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d. at 1384-1385.

Notably, Applicant specifically explains in the Description of the Related Art section that "the crystalline structure of apatites such as hydroxyapatite [ $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ ] closely resembles the crystalline structure of biosystems such as bone and teeth, and apatites have been confirmed as displaying good bioaffinity, enabling them to be integrated with biosystems inside living bodies. Taking advantage of this characteristic, hydroxyapatite is conventionally used to coat the surface of metals such as stainless steel and titanium alloy, or ceramics such as zirconia, which are used as the base materials for biomaterials such as artificial bone, artificial teeth roots, and artificial joints, thereby forming a surface layer that imparts bioaffinity to the biomaterial." *See* page 1, lines 11-19. In addition, many methods have been proposed for forming this surface layer of hydroxyapatite on the base material. For example, one earlier method involved "injecting calcium ions into the surface of a titanium base material, and then immersing the base material in an artificial body fluid". *See, e.g.,* page 1, lines 20-21 and page 2, lines 7-8.

Again, independent claim 6 calls for a film that is produced by applying a coating liquid, which comprises a polysilazane and a calcium compound, on a base material. That film has apatite forming ability in an artificial body fluid.

Accordingly, when biomaterial includes, in part, a film that has "apatite forming ability", as is claimed by Applicant, one of ordinary skill in the art would naturally conclude, at least as a result of the disclosure contained in the specification, that the film forms an apatite, for example, on a base material when exposed to artificial body fluid. Thus, it is submitted that "apatite forming ability" is not at all unclear, particularly to one having ordinary skill in the art. Further to that end, Exhibits A-C, which are discussed next, yet further help to illustrate that the term "apatite forming ability" is not unclear but rather well known and understood by one of ordinary skill in the art.

- Exhibit A: Toshiki Miyazaki et al., Apatite-forming ability of Niobium oxide gels in a simulated body fluid, *Journal of the Ceramic Society of Japan*, 2001, Vol.109, No.11, pages 929 to 933.
- Exhibit B: Japanese Patent Publication No.4017836, filing date: 02.05.2001, with English Abstract and English translation of Claim 1.
- Exhibit C: Besim Ben-Nissan et al., "Chapter 6: Bioceramics: An Introduction", *Engineering Materials for Biomedical Applications*, Edited by Swee Hin Teoh Swee Hin, © World Scientific 2004, ISBN:9812560610, page 6-17.

Concerning Exhibit A, the term "apatite-forming ability" is quickly recognized in the title, "Apatite-forming ability of Niobium oxide gels in a simulated body fluid". [underlining for emphasis]. As suggested by the title, Exhibit A readily and fully discusses formation of apatite layers, or the apatite-forming ability, of niobium oxide gels when used in a simulated body fluid (SBF). In view thereof, not only is the term "apatite forming ability" understandable in claim 6 via Applicant's specification, that term is well known and understood by one of ordinary skill in the

art, as evidenced at least by Exhibit A.

In addition, it is simply noted that Exhibit A further states under section 2.2 at page 930 that a simulated body fluid (SBF) "was prepared by dissolving reagents of NaCl,  $\text{NaHCO}_3$ , KCl,  $\text{K}_2\text{HPO}_4 \cdot 3\text{H}_2\text{O}$ ,  $\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$ ,  $\text{CaCl}_2$  and  $\text{Na}_2\text{SO}_4$  into distilled water to adjust ion concentrations to:  $\text{Na}^+$  142.0,  $\text{K}^+$  5.0,  $\text{Mg}^{2+}$  1.5,  $\text{Ca}^{2+}$  2.5,  $\text{Cl}^-$  147.8,  $\text{HCO}_3^-$  4.2,  $\text{HPO}_4^{2-}$  1.0,  $\text{SO}_4^{2-}$  0.5 mM." In comparison, the term "artificial body fluid" in the present application refers to "inorganic ion concentrations substantially equal to those of human body fluids ( $\text{Na}^+$ : 142.0 mM,  $\text{K}^+$ : 5.0 mM,  $\text{Mg}^{2+}$ : 1.5 mM,  $\text{Ca}^{2+}$ : 2.5 mM,  $\text{Cl}^-$  147.8 mM,  $\text{HCO}_3^-$  4.2 mM,  $\text{HPO}_4^{2-}$  1.0 mM,  $\text{SO}_4^{2-}$  0.5mM)". In other words, the artificial body fluid disclosed in the present application, and further now recited in claim 6 to more clearly define the invention, has the same components as the simulated body fluid (SBF) disclosed in Exhibit A.

Further concerning Exhibit B, the term "apatite-forming ability" can be found in Claim 1 of the granted Japanese patent and is more specifically discussed in the abstract, for example, as pertaining to a titanium oxide/organic polymer composite suitable as artificial bone. See the English translation of Claim 1 and abstract.

Finally, with respect to Exhibit C, under 6.5.2 Simulated Body Fluid (SBF), this document states that "formation of the bone-like apatite layer on bioactive materials can be produced in a simulated body fluid (SBF) which has ion concentrations almost equal to those of the human blood plasma. Currently most bioceramics research studies use this solution to measure an artificial material's bioactivity by examining the apatite-forming ability on its surface when immersed in SBF." [underlining for emphasis].

In view of all of the above, Applicant submits that the term "apatite forming ability", as used in the claims, is not all unclear in view of the present application and is further readily understood in the art. And, as discussed above, claim 6 has been further amended to more clearly define the invention. In particular, claim 6 now recites that the film has an apatite forming ability in an artificial body fluid.

Thus, for all of the above reasons, the present rejection is overcome and must be withdrawn.

#### **No Prima Facie Case**

In accordance with the aforementioned, it is submitted that the claims as pending are patentable. In that regard, the additional art cited by Examiner as being of interest is submitted not to change the situation.

#### **Conclusion**

As a result of the remarks given herein, Applicant submits that the rejections of the pending claims have been overcome. Therefore, Applicant respectfully submits that this case is in condition for allowance and request allowance of the pending claims.

If the Examiner believes any detailed language of the claims requires further discussion, he is respectfully asked to telephone the undersigned attorney so that the matter may be promptly resolved. Applicant also has submitted all fees believed to be necessary herewith. Should any additional fees or surcharges be deemed necessary, the Examiner has authorization to charge fees or credit any overpayment to Deposit Account No. 23-3000.

Respectfully submitted,  
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